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USSN: 10/634,176
Dkt. No.: 8600-0006.01
00-207 02 US
PATENT

CERTIFICATE OF MAILING PURSUANT TO 37 CFR § 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on **February 23, 2005.**

2/23/05 Michelle Hodson
Date Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Examiner: U. Ho
TEOH & WALLACE	Group Art Unit: 3731
Serial No.: 10/634,176	Confirmation No.: 7120
Filing Date: August 4, 2003	Customer No.: 20855
Title: NON-OVERLAPPING SPHERICAL THREE-DIMENSIONAL COIL	

TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Sir:

Transmitted herewith for filing, please find the following documents:

x Supplemental Brief on Appeal (11 pages) including attached Appendix A (3 pages) along with attached Appendix B (2 pages) and Appendix C (4 pages) *in triplicate*

x Return receipt postcard

The fee is calculated as follows:

	NO. OF CLAIMS	CLAIMS PREVIOUSLY PAID FOR	EXTRA CLAIMS	RATE	FEE
Total Claims	23	- 23	0	x $50.00	$0
Independent Claims	2	- 3	0	x $200.00	$0
Multiple dependent claims not previously presented, add $360.00					$0
Total Amendment Fee					$0
Small Entity Reduction (if applicable)					$0
TOTAL FEE DUE					$0

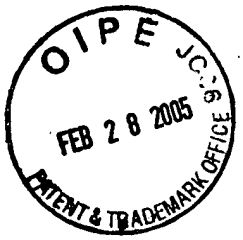
The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 18-1648.

Respectfully submitted,

Date: February 23, 2005

By: 
Dahna S. Pasternak
Registration No. 41,411

ROBINS & PASTERNAK LLP
1731 Embarcadero Road, Suite 230
Palo Alto, CA 94303
Tel.: (650) 493-3400
Fax: (650) 493-3440



USSN 10/634,176
8600-0006.01
00-0207 02 US

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SUPPLEMENTAL BRIEF ON APPEAL

ROBINS & PASTERNAK LLP
1731 Embarcadero Road
Suite 230
Palo Alto, CA 94303

Attorney for Appellants

TABLE OF CONTENTS

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SUPPLEMENTAL BRIEF ON APPEAL

Mail Stop Appeal Brief
Commissioner for Patents
Alexandria, VA 22313

Sir:

INTRODUCTION

Appellants submit in triplicate their supplemental brief on appeal in accordance with 37 C.F.R. §1.193(b)(2)(ii). A Notice of Appeal was filed October 4, 2004 and a Brief on Appeal was filed on November 2, 2004. Prosecution on the merits was reopened in a non-final Office Action mailed on January 25, 2005 and all claims were non-finally rejected under 35 U.S.C. § 112, second paragraph and 35 U.S.C. § 102. Pursuant to 37 C.F.R. § 1.193(b)(2)(ii) and submission of this Supplemental Brief on Appeal, Appellants request reinstatement of the appeal.

I. REAL PARTIES IN INTEREST

Scimed Life Systems, Inc., a division of Boston Scientific Corporation, is the real party in interest in this matter.

II. RELATED APPEALS AND INTERFERENCES

Appellants are not aware of any related appeals or interferences.

III. STATUS OF THE CLAIMS

Appealed claims 1-23 were originally filed with the above-referenced case (hereinafter "the application") on August 4, 2003. The application is a continuation of U.S. Serial No. 09/691,954, filed October 18, 2000, now U.S. Patent No. 6,635,069.

A Notice of Appeal was filed October 4, 2004 and a Brief on Appeal was filed on November 2, 2004. Prosecution on the merits was reopened in an Office Action mailed on January 25, 2005. Pursuant to 37 C.F.R. § 1.193(b)(2)(ii) and submission of this Supplemental Brief on Appeal, Appellants request reinstatement of the appeal.

Claims 1-8 and 10-23 remain rejected under 35 U.S.C. § 102. New grounds of rejection of claims 1-23, based on 35 U.S.C. § 112, second paragraph set forth in the Office Action mailed on January 25, 2005 reopening prosecution after appeal. Thus, claims 1-23 are pending as shown in Appendix A.

IV. STATUS OF THE AMENDMENTS

The status of the amendments filed in the Brief on Appeal submitted November 2, 2004 are applicable and are hereby incorporated by reference. Pursuant to 37 C.F.R. § 1.193(b)(2)(ii), no new amendments are made herein.

V. SUMMARY OF THE CLAIMS

The summary of the claims filed in the Brief on Appeal submitted November 2, 2004 is applicable and is hereby incorporated by reference.

VI. ISSUES ON APPEAL

1. Whether pending claims 1-23 are sufficiently definite under 35 U.S.C. § 112, second paragraph.

2. Whether pending claims 1-8 and 10-23 are anticipated by U.S. Patent No. 6,638,291 under 35 U.S.C. § 102(e).

Appellants note that Issue (2) as set forth above is unchanged and was addressed in the Brief on Appeal filed on November 2, 2004.

Issue (1) is a new ground of rejection set forth in the Office Action mailed on January 25, 2005, in response to the Brief on Appeal.

VII. GROUPING OF CLAIMS

Appellants herein incorporate by reference the statements made in the Brief on Appeal filed November 2, 2004 regarding the Grouping of the Claims.

VIII. ARGUMENTS

1. The Recitation of "Non-overlapping loops" in the Claims is Not Indefinite

Claims 1-23 were newly rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite. (Office Action mailed January 25, 2005, page 3). In particular, the term "non-overlapping loops" was alleged to be unclear as it is "not defined by the claim" and because:

> the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification disclose non-overlapping loop being do not overlap itself or with each other. Figure 5 show loops are spaced apart but overlap with each other in three-dimensional configuration when view fact-on in

> three-dimensions. The specification fails to disclose what "non-overlapping loops" is really meant in three-dimensions view.

It is axiomatic that the definiteness requirement of 35 U.S.C. § 112, second paragraph is satisfied if it is clear to the skilled artisan what is meant by a particular claim term. *See, e.g., In re Marosi,* 218 USPQ 289 (Fed. Cir. 1983). Further, the definiteness and clarity of claim language must be analyzed, not in a vacuum, but in light of (1) the content of the particular disclosure; (2) the teachings of the art; and (3) the claim interpretation that would be given by one possessing ordinary skill in the pertinent art at the time the invention was made. *See, e.g., W.L. Gore & Assocs., Inc. v. Garlock, Inc.,* 220 USPQ 202 (Fed. Cir. 1983). In other words, the terms at issue must be read in context of the application and field of endeavor.

Applying this well-settled case law the case on appeal, it is plain that the assertion by the Examiner that a claim term be defined in the claim itself is in error. Moreover, there is absolutely no supporting basis for the assertions that Figure 5 somehow shows overlapping loops or that the specification fails to disclose non-overlapping refers only to three-dimensional view.

In fact, as repeatedly noted on the record, the term "non-overlapping loops" is amply defined in the specification to refer to a structure in which the individual loops do not crossover (intersect) each other in the same plane. The record is clear that the term does not refer to the apparent intersection of loops in different planes when the three-dimensional structure is viewed from one angle. Indeed, it is clear from the specification as filed that the term "non-overlapping" refers to the nature of the single linear strand of material (*e.g.,* wire) as it is wound into the substantially spherical three-dimensional device. In particular, the linear strand is wound such that is forms non-overlapping loops when allowed to self-form into relaxed configuration. In other words, the loops, which delineate the three-dimensional configuration, do not cross over themselves and are not intertwined.

The concept of non-overlapping loops is illustrated in Figure 5 and described throughout the specification, for example on page 5, lines 9 to 15, stating:

> The three-dimensional configuration is made up of a plurality of loops of a first configuration. However, unlike other three-dimensional vaso-occlusive devices, the loops of the wire making up the three-dimensional configuration of the device as deployed do not overlap.

Thus, the term "non-overlapping loops" refers to a device in which the looped linear strand making up the relaxed configuration does not cross over itself in the relaxed configuration. The term does not, as suggested by the Examiner, refer to loops that overlap each other in three-dimensional views, that is, by viewing loops of different planes as somehow "intersecting." In view of the specification and Figures as filed, it would be clear to any engineer what is meant by the term "non-overlapping loops" as used in the pending claims.

Further evidence of the meaning and definiteness of this term is found in the record in a Declaration by co-inventor Michael Wallace, made of record in the parent application, U.S. Serial No. 09/691,954, now U.S. Patent No. 6,635,069. Co-inventor Michael Wallace unequivocally states that an engineer working in this field would understand the meaning as well as the metes and bounds of the term "non-overlapping." For convenience, a copy of this Declaration is attached hereto as Appendix C. Michael Wallace's Declaration is not new evidence inasmuch as it was timely presented and part of the record of this and the parent application.

In sum, when properly read in light of the specification, those skilled in the art would be more than amply apprised as to the metes and bounds of the term "non-overlapping loops," as set forth in the claims. Accordingly, withdrawal of this rejection is respectfully requested.

2. Anticipation Has Not Been Established

The rejection of claims 1-8 and 10-23 as allegedly anticipated under 35 U.S.C. § 102(e) by U.S. Patent No. 6,638,291 (hereinafter "Ferrera") was again restated in the Office Action mailed on January 25, 2005.

(a) Ferrera, like other devices of the art, does not disclose devices with non-overlapping loops

Appellants herein incorporate by reference the arguments made in the Brief on Appeal filed November 2, 2004 regarding 35 U.S.C. § 102, including the various schematic diagram depictions (in two- and three-dimensions) showing how the loops of Ferrera's device are overlapping and, accordingly, differ in structure from the devices as claimed. Simply put, although there are many ways to illustrate it, the fact remains that the loops of Ferrera's device

are overlapping. Applicants regret that their attempts to illustrate the non-overlapping structure have not been understood by the Examiner (Office Action, January 25, 2005, page 2).

In an effort to show the differences in yet another way, Appellants present a comparison of Figures from Ferrera, the prior-art device shown in U.S. Patent No. 6,322,576 (Reference AU-1 in IDS filed August 4, 2003, hereinafter "the '576 patent") and Figure 5 of the application on appeal. This comparison shows how Ferrera's overlapping structure is a similar design to that disclosed in '576 patent, which was cited by the Office during prosecution of the parent of the application on appeal (*i.e.*, U.S. Patent No. 6,635,069). In the parent application, once the Examiner understood how an engineer would plainly understand the term "non-overlapping" to exclude the structures disclosed in the '576 patent, the claims were properly allowed (*see,* Declaration of Michael Wallace, Appendix C). Thus, the following comparison of Figures from the '576 patent, Ferrera, and the case at hand provides yet another demonstration that Ferrera, like the '576 patent, discloses structures that are overlapping and are, therefore, unlike the claimed devices:

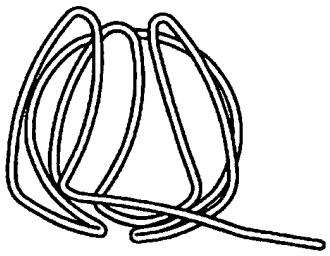


FIG. 4C of
U.S. Patent No. 6,322,576

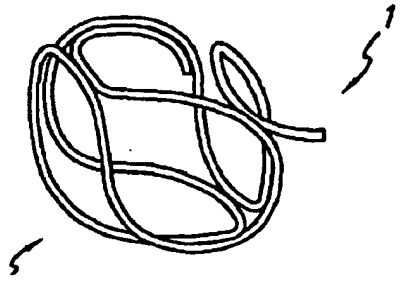


FIG. 2 of
Ferrera

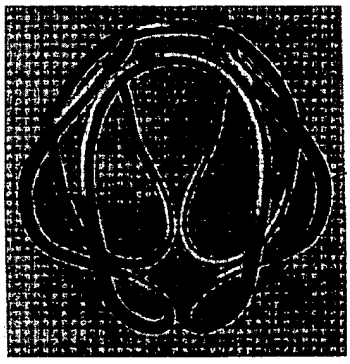


FIG. 5 of
Application on Appeal

In sum, this side-by-side comparison shows in yet another way that Ferrera's devices include loops that overlap and intersect at various points. Accordingly, Ferrera cannot anticipate the claims as pending.

(b) Ferrera teaches orthogonal devices, which are necessarily overlapping

Appellants further note that the Office Action mailed January 25, 2005, which reiterated the rejection based on Ferrera, did not address the fact that Ferrera explicitly teaches that his device, particularly the device shown in Figs. 2, 3A and 3B as cited by the Examiner, are "orthogonal" (*i.e.,* intersecting) (Ferrera, at col. 6, lines 2-5, emphasis added):

> As is illustrated in FIG. 2, in a presently preferred embodiment, the three dimensional portion of the vasooccclusive device is **orthogonal**...

Merriam-Webster's on-line dictionary defines "orthogonal" as "intersecting or lying at right angles ... having perpendicular slopes or tangents at the point of intersection." (See, Appendix B of Brief on Appeal filed November 2, 2004 and attached hereto). Quite simply, and in stark contrast to the claimed devices, Ferrera teaches **explicitly** that the devices shown in Figures 2-3 comprise intersecting/overlapping structures.

Thus, it is erroneous to assert that there are no structural limitations distinguishing the claimed devices from Ferrera's or that Ferrera's device is "capable of being used as claimed if one desires to do so." *See,* Office Action mailed January 25, 2005, page 4. In reality, Ferrera's device has intersecting loops and, as such, is not capable of being used as claimed.

The evidence previously made of record, including Ferrera's own teachings, the Examiner's admission, Appellants' textual explanations of three-dimensional structures and description of a simple, path-tracing exercise that can be readily repeated again and again to give the same results, establishes that the rejection is entirely unsustainable. Ferrera does not describe or demonstrate a device as claimed, in which the loops making up the three-dimensional configuration do not overlap and, indeed teaches that FIGs. 2-3 show such intersecting structures. Accordingly, this reference cannot anticipate any of the pending claims.

3. Additional Arguments Regarding Separately Grouped Claims

Appellants herein incorporate by reference the additional arguments made in the Brief on Appeal filed November 2, 2004 regarding separately grouped claims.

CONCLUSION

Applicants submit that the claims are in condition for allowance and request early notification to that effect. If the Examiner has any further issues or wishes to discuss any of the foregoing, she is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

Date: February 23, 2005

By: _____

Dahna S. Pasternak
Attorney for Appellants
Registration No. 41,411

ROBINS & PASTERNAK LLP
1731 Embarcadero Road, Suite 230
Palo Alto, CA 94303
Tel.: (650) 493-3400
Fax: (650) 493-3440

APPENDIX A

LIST OF CLAIMS ON APPEAL

1. (original): A vaso-occlusive device comprising at least one substantially linear strand of a vaso-occlusive member wound into a stable, three-dimensional relaxed configuration comprising a plurality of non-overlapping loops, wherein said relaxed configuration self-forms upon release from a restraining member.

2. (original): The vaso-occlusive device of claim 1, wherein the relaxed configuration fills a body cavity.

3. (original): The vaso-occlusive device of claim 1, wherein the relaxed configuration approximates a sphere.

4. (original): The vaso-occlusive device of claim 1, comprising between 6 and 20 loops.

5. (original): The vaso-occlusive device of claim 1, comprising between 6 and 12 loops.

6. (original): The vaso-occlusive device of claim 1, wherein the vaso-occlusive member comprises a metal selected from the group consisting of platinum, palladium, rhodium, gold, tungsten and alloys thereof.

7. (original): The vaso-occlusive device of claim 1, wherein the vaso-occlusive member comprises a stainless steel or super-elastic metal alloy.

8. (original): The vaso-occlusive device of claim 1, wherein the vaso-occlusive member comprises nitinol.

9. (original): The vaso-occlusive device of claim 1, further comprising additional filamentary material attached to the vaso-occlusive member.

10. (original): The vaso-occlusive device of claim 1, further comprising a deployment tip attached to at least one of the two ends of the vaso-occlusive member.

11. (original): The vaso-occlusive device of claim 10, wherein the deployment tip comprises a mechanically detachable end adapted to attach and detach from a pusher.

12. (original): The vaso-occlusive device of claim 10, wherein the deployment tip comprises an electrolytically detachable end adapted to detach from a pusher by imposition of a current on the pusher.

13. (original): A method of occluding a body cavity comprising introducing a vaso-occlusive device according to claim 1 into the body cavity.

14. (original): The method of claim 13, wherein the body cavity is an aneurysm.

15. (original): A method of making a non-overlapping three-dimensional vaso-occlusive device according to claim 1, the method comprising

(a) winding a substantially linear strand of a vaso-occlusive member around a winding mandrel, said winding comprising a winding pattern that produces a non-overlapping three-dimensional vaso-occlusive device according to claim 1; and

(b) heating the mandrel and vaso-occlusive member to produce said vaso-occlusive device.

16. (original): The method of claim 15, wherein the winding pattern is a Figure 8 or hourglass.

17. (original): The method of claim 15, wherein the winding mandrel comprises a sphere having grooves adapted to fit the substantially linear strand.

18. (original): The method of claim 15, wherein the winding mandrel comprises a cylinder.

19. (original): The method of claim 15, wherein the winding mandrel comprises a sphere having a plurality of pins on the surface thereof.

20. (original): The method of claim 15, wherein the winding mandrel comprises a tetrahedron.

21. (original): The method of claim 15, wherein the winding mandrel comprises 3 intersecting posts which form a 6 post structure and wherein each post is at approximately 90 relative to the adjacent posts.

22. (original): The method of claim 21, wherein at least one post has a round cross section.

23. (original): The method of claim 21, wherein each post has a round cross section.

Appendix B

Merriam-Webster Online Dictionary

Thesaurus

One entry found for **orthogonal**.

Main Entry: **or thog o nal**
Pronunciation: or-'thä-g&-n&l
Function: *adjective*
Etymology: Middle French, from Latin *orthogonius,* from Greek *orthogOnios,* from *orth-* + *gOnia* angle -- more at -GON

1 a : intersecting or lying at right angles **b :** having perpendicular slopes or tangents at the point of intersection <*orthogonal* curves>
2 : having a sum of products or an integral that is zero or sometimes one under specified conditions: as **a** *of real-valued functions* **:** having the integral of the product of each pair of functions over a specific interval equal to zero **b** *of vectors* **:** having the scalar product equal to zero **c** *of a square matrix* **:** having the sum of products of corresponding elements in any two rows or any two columns equal to one if the rows or columns are the same and equal to zero otherwise **:** having a transpose with which the product equals the identity matrix
3 *of a linear transformation* **:** having a matrix that is orthogonal **:** preserving length and distance
4 : composed of mutually orthogonal elements <an *orthogonal* basis of a vector space>
5 : statistically independent
- or thog o nal i ty /-"thä-g&-'na-l&-tE/ *noun*
- or thog o nal ly /-'thä-g&-n&l-E/ *adverb*

For **More Information on "orthogonal" go to Britannica.com**
Get the **Top 10 Search Results for "orthogonal"**

Pronunciation Symbols

Appendix C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Examiner: Gloria M. Hale
Teoh et al.	Group Art Unit: 3765
For: **NON-OVERLAPPING SPHERICAL THREE-DIMENSIONAL COIL**	Confirmation No.: 5405
Serial No.: 09/691,954	
Filed: October 18, 2000	**DECLARATION OF MICHAEL WALLACE PURSUANT TO 37 C.F.R.§ 1.132**
Atty. Docket No.: 8600-0006 (00-207)	

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, Michael Wallace, hereby declare as follows:

1. I am currently Director of Research and Development at Boston Scientific/Target. I have held this position since June 2000. I am extremely familiar with implantable devices such as vaso-occlusive devices, having actively worked in this discipline for over eight (8) years. I have co-authored numerous publications and patents in the field of vaso-occlusive coils.

2. I am a co-inventor of Patent Application Serial No. 09/691,954 for "NON-OVERLAPPING SPHERICAL THREE-DIMENSIONAL COIL" (hereinafter "the specification") and am familiar with the currently pending claims. I am also a co-inventor of U.S. Patent No. 6,322,576 (hereinafter "the '576 patent", which disclosure is identical to WO 99/09893) and am familiar with the disclosure and claims of this patent and corresponding International publication.

3. I understand that the pending claims are directed to vaso-occlusive devices that have a stable, self-forming relaxed configuration approximating a sphere. The device is made up of a plurality of loops. Notably, the loops do not overlap with one another. Also claimed are methods of making and using these devices.

4. It is my opinion that the '576 patent, of which I am a co-inventor, does not describe, demonstrate or suggest the devices or methods as set forth in the pending claims. I base these opinions on the facts set forth below; however, I call attention to the fact that the '576 patent does not describe devices made up of **non-overlapping** loops.

5. It is clear from the specification as filed that the term "non-overlapping" refers to the nature of the single linear strand of material as it is wound into the substantially spherical three-dimensional device. In particular, the linear strand is wound such that is forms non-overlapping loops when allowed to self-form into relaxed configuration. In other words, the loops, which delineate the three-dimensional configuration, do cross over themselves and are not intertwined. The concept of non-overlapping loops is illustrated in Figure 5 and described throughout the specification, for example on page 5, lines 9 to 15, stating:

> The three-dimensional configuration is made up of a plurality of loops of a first configuration. However, unlike other three-dimensional vaso-occlusive devices, the loops of the wire making up the three-dimensional configuration of the device as deployed do not overlap.

Thus, the term "non-overlapping loops" refers to a device in which the looped linear strand making up the relaxed configuration does not cross over itself in the relaxed configuration. In view of the specification and Figures as filed, it would be clear to any engineer what is meant by the term "non-overlapping loops" as used in the pending claims.

6. Furthermore, it is my opinion that the text or Figures of '576 patent (and its International counterpart WO 99/09893) do not describe, demonstrate or suggest the claimed compositions and methods. The application at issue discloses and claims devices approximating the shape of a sphere in which the loops of the first configuration are non-overlapping. There is no disclosure in the '576 patent that would lead any engineer working in this area to conclude non-overlapping (or non-intertwined) loops would be desirable for any reason. Rather, as shown in Figures 2, 4A-D, 6, 7C, 10A-B, 12, 14, 16, 18A-B, and 22B, the '576 patent teaches and suggest devices in which the loops are clearly intertwined and overlapping. Indeed, when the specification was filed we noted that the non-overlapping structure differed from the devices of the '576 patent, for example in deployment:

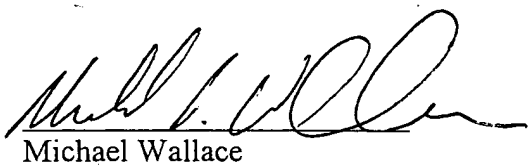
> The self-forming, non-overlapping three-dimensional coil designs of the present invention are particularly useful in treating aneurysms. The non-overlapping loop design described herein provides an improvement over known devices, for example in terms of ease of deployment. Available three-dimensional coils are made up of a plurality of overlapping and intertwined loops. Upon deployment from a substantially linear configuration these devices often rotate or whip undesirably during deployment. Whipping refers to the phenomena where a device stores energy imparted by a user and then releases the energy very quickly. For example, vaso-occlusive devices are often deployed and manipulated at the target site using a guidewire controlled by the operator at a proximal location. Whipping occurs when the rotation

imparted by the operator on the guidewire does not result in the same 1:1 rotation of the distal end of the device. Rather, the device stores up the rotational energy and then may suddenly release the energy and rotate suddenly in a short time. Rotation, whipping and other problems associated with available vaso-occlusive devices can impede formation of the three-dimensional relaxed configuration. In contrast, the non-overlapping configuration of the devices described minimizes rotation and whipping upon deployment and promotes formation of a three-dimensional configuration that substantially conforms to the target vessel. (page 5, line 26 to page 6, line 14 of the specification).

The '576 patent and WO 99/09893 do not disclose or suggest devices in which the relaxed, substantially spherical, configuration is made up of non-overlapping loops, as set forth in the pending claims. Accordingly, I do not believe that the '576 patent describes the devices claimed by myself and the other co-inventor in the pending application.

7. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

4/14/03
Date


Michael Wallace